SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF NEW YORK

BRASSICA PROTECTION PRODUCTS LLC,

Plaintiff,

-against-

CAUDILL SEED & WAREHOUSE CO, INC. d/b/a CAUDILL SEED CO.,

Defendant.

Index No.

Purchased:

The basis of venue is New York County pursuant to Contract.

**SUMMONS** 

To the above-named Defendant:

YOU ARE HEREBY SUMMONED to answer the Complaint in this action and to serve a copy of your answer, or, if the Complaint is not served with this summons, to serve a notice of appearance, on the Plaintiff's Attorneys within 20 days after the service of this summons, exclusive of the day of service (or within 30 days after the service is complete if this summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

Dated: New York, New York August 6, 2007

BINGHAM McCUTCHEN LLP

Edward L. Powers 399 Park Avenue

New York, New York 10022

(212) 705-7000

Attorneys for Plaintiff

TO:

Caudill Seed & Warehouse Co., Inc. d/b/a Caudill Seed Co. 1402 W. Main Street Louisville, Kentucky 40203

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SUPREME COURT OF THE STATE OF NEW YORK

COUNTY OF NEW YORK

BRASSICA PROTECTION PRODUCTS LLC,

Plaintiff,

- against -

CAUDILL SEED & WAREHOUSE CO., INC. d/b/a CAUDILL SEED CO.,

**:** 

Defendant.

Plaintiff BRASSICA PROTECTION PRODUCTS LLC, by and through its attorneys BINGHAM McCUTCHEN LLP, as and for its COMPLAINT against defendant CAUDILL SEED & WAREHOUSE CO., INC. d/b/a CAUDILL SEED CO., hereby says the following:

#### THE PARTIES

- 1. Plaintiff Brassica Protection Products LLC ("BPP") is a Delaware limited liability company engaged in the business of, among other things, the development and promotion of certain chemoprotective dietary supplement products based upon the extraction and processing of glucosinolates or isothiocyanates from cruciferous seeds, sprouts, and fresh cruciferous sprouts and chemoprotective foods. BPP maintains its principal place of business in Baltimore, Maryland.
- 2. Defendant Caudill Seed and Warehouse Co., Inc. ("CSC") is a corporation organized and existing under the laws of the State of Kentucky, engaged in the business of development and sale of sprouting seeds and natural foods.

3. This dispute arises from a written agreement relating to obligations from a transaction covering in the aggregate in excess of \$1 million. In their written agreement, plaintiff BPP and defendant CSC chose the application of New York law, submitted to the jurisdiction of this Court, and designated the New York Secretary of State as their non-exclusive agent for service of process in any proceeding brought in this Court.

# **SUMMARY OF ALLEGATIONS**

- 4. This is an action in law and equity to recover royalties owed by CSC to BPP and to enjoin CSC preliminarily and permanently from manufacturing and distributing products that utilize BPP's confidential information, know-how, or patent rights, or that bear BPP's trademarks.
- 5. By Sublicense, Manufacture and Distribution Agreement as of December 6, 2004 (the "Agreement"), BPP granted CSC a non-exclusive sublicense to use the BPP patents, patent rights, and know-how, and a license to use certain BPP trademarks, for the purpose of manufacturing, distributing and selling certain products in the United States and Canada, which consist of or comprise extracts of glucosinolates or isothiocyanates from cruciferous seeds or sprouts, hereinafter referred to as "SGS-containing products."
- 6. In accordance with the December 6, 2004 agreement, BPP conveyed its confidential and proprietary information regarding SGS-containing products to CSC.
- 7. CSC agreed to manufacture the SGS-containing products in accordance with current good manufacturing practices ("cGMP" or "GMP") and written specifications, as established by BPP.
- 8. Because of CSC's material breaches of the Agreement, including CSC's failure to manufacture SGS-containing products in accordance with GMP and contractual quality control

specifications, BPP notified CSC by letter dated June 8, 2007 that the Agreement would be terminated on July 12, 2007, unless CSC cured its breaches of the Agreement.

- 9. During the 30-day cure period, CSC did not seek to cure its breaches of the Agreement and instead sought and requested a short extension of time delaying the effective date of the termination of the Agreement for the sole purpose of negotiating a possible new sublicense agreement with BPP. BPP agreed to defer the termination date for nine days, but strictly for that purpose. The letter agreeing to the extension stated: "If on or before July 20, 2007, BPP and CSC do not enter into a new . . . agreement, then the [June 8, 2007] Letter shall continue in effect and the Effective Date [of termination] shall be July 21, 2007.
  - 10. CSC and BPP did not enter into a new sublicense agreement.
  - 11. The Agreement terminated on July 21, 2007.

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- 12. On July 20, 2007, CSC transmitted a letter to BPP in which CSC denied that it had materially breached the Agreement, denied that CSC is subject either to the contractual quality control specifications or to GMP standards and regulations, and stated that it intended to continue its operations—including its manufacture and distribution of SGS-containing products—under the Agreement, notwithstanding BPP's termination of the Agreement.
- 13. CSC's continued manufacture, distribution, and sale of SGS-containing products constitutes an improper, unauthorized use of BPP's confidential information, patents, trademarks, and business reputation causing irreparable harm to BPP, and is in direct breach of the post-termination provisions of the Agreement. In particular, the Agreement provides that upon termination of the Agreement, all rights granted to CSC revert to BPP "and CSC shall cease the production, manufacture, distribution, sale, use or advertisement" of the SGS-containing products.

- 14. The Agreement permits CSC to sell its existing inventory of SGS-containing products during the 90-day period following termination of the Agreement, but only if CSC promptly delivers a schedule of its existing inventory to BPP, and BPP then declines to purchase that inventory. CSC has failed to deliver a schedule of its existing inventory to BPP and therefore has no right to sell its inventory of the SGS-containing products.
- 15. CSC has not paid BPP the contractually specified royalty payments for the second quarter of 2007 or the prorated minimum royalty payment due under the Agreement. These payment obligations cover the period that the Agreement was in effect. In addition, CSC is indebted to BPP for CSC's unauthorized, ongoing manufacture and distribution of SGS-containing products despite the July 21, 2007 termination of the Agreement.

# **FACTS**

### The JHU License

- Hopkins University School of Medicine were able to identify and quantify the components in broccoli and other cruciferous vegetables that boost the human body's enzyme systems detoxifying carcinogens before they can cause damage to cells. This research led to the subsequent discovery that the amounts of these protective compounds were highly variable in plants, but that selection and growing of small plants (sprouts) could provide much higher and more consistent amounts. Johns Hopkins and the scientists who made this discovery were issued a series of US (and international) patents starting in 1998. As described in paragraph 18, below, the patent rights were exclusively licensed to BPP in 1998.
- 17. The patented glucosinolates and isothiocyanates from cruciferous sprouts and seeds are among the strongest inducers of Phase 2 detoxifying enzymes found in plants and also contain long-lasting antioxidant and anti-inflammatory activities.

18. By license agreement effective March 10, 1998 (the "JHU License"), John Hopkins University granted to BPP an exclusive license to make, have made, use, and sell any "Licensed Products" in the United States and worldwide. Licensed Products are defined in section 1.2 of the JHU License as:

any material, compositions, drug, ingredient, extract, supplement from extracts, fresh food or product derived from fresh foods, or any other product, the manufacture, use or sale of which would constitute, but for the license granted to the Company [BPP] pursuant to this Agreement, an infringement of a claim of PATENT RIGHTS (infringement shall include, but is not limited to, direct contributory or inducement to infringe).

#### The CSC Sublicense Agreement

- 19. Pursuant to the JHU License, BPP expended significant resources in developing the proprietary technology and expertise to extract these active ingredients from seeds and thus make them available for introduction as food ingredients and supplements.
- 20. BPP and CSC entered into the Agreement, by which, among other things, BPP sublicensed to CSC BPP's technology and patent rights to SGS-containing products. A true and correct copy of the Agreement entered into as of December 6, 2004 is annexed to the Complaint as Exhibit A.
- Ingredient Product and Finished Product, collectively, "Product." Ingredient Product is defined in section 1.17 of the Agreement as:

extracted or purified glucosinolate or isothiocyanate to be included as an ingredient in a capsule, tablet, pill or similar form ... which is produced and/or manufactured using BPP Know-How and the BPP Patents or Patent Rights.

22. Finished Product is defined in section 1.12 of the Agreement as:

capsules, tablets, pills or similar delivery conveyors that contain extracted or purified glucosinolate or isothiocyanate ... which are produced and/or manufactured using BPP Know-How and the BPP Patents or Patent Rights.

23. Pursuant to the Agreement, BPP also provided CSC with BPP's Know-How with respect to the Product, defined in section 1.4 as:

all current and future data and proprietary rights of any type whatsoever (other than patents or patent applications, including the BPP Patents or Patent Rights), in any tangible or intangible form whatsoever, that is owned (or to the extent owned) by BPP or that BPP has the unrestricted right to use, that is material to the production, manufacture, storage, filling, packaging and shipping of the Product, including, without limitation, technology, Labeling, inventions, practices, methods, techniques, specifications, drawings, plans, formulations, formulae, knowledge, skill, experience, technical and non-technical data, test data (including test or stability data), results of studies, technical drawings and related copyrights, consumer and market research data and other similar information.

- 24. BPP also licensed CSC to use the certain BPP trademarks and trademark applications listed on Schedule 1.35 to the Agreement.
  - 25. The term of the Agreement was set forth in Section 10.1:

This Agreement shall commence on December 6, 2004 and continue thereafter until the earliest of (i) the expiration of the last patent included in the BPP Patents, (ii) the determination by a court or administrative agency of competent jurisdiction that all claims of the last patent within the BPP Patents is invalid or unenforceable or (iii) the date this Agreement is terminated in accordance with Section 10.2 hereof (the "Term").

## **Quality Control**

26. The Agreement contains a number of quality control provisions to ensure the purity and quality of the Product as well as the ability to monitor and track all phases of the manufacturing of the Product in the event of any problems or unexpected events. These include

sections 3.1 (Standards), 3.2 (Manufacturing Facility), 3.8 (Product Specifications Amendments) and 6.2 (Manufacturing Records). During the negotiations leading up to the Agreement, BPP emphasized to CSC's President and Chief Executive Officer, Dan Caudill ("Caudill"), that CSC would be required to manufacture the Product in conformance with strict quality control standards because the Product was being made and sold for human consumption, because BPP intended to be an industry leader in providing chemoprotective products, and because it was critical to BPP that its name and reputation, as well as that of Johns Hopkins University, would be used only in association with high quality products.

27. Consistent with the foregoing, Section 3.1 (Standards) of the Agreement states:

> CSC agrees to produce or caused to be produced. manufacture or cause to be manufactured, fill, test, package, label, store, ship, supply, dispose and otherwise handle the Product, and to perform its obligations hereunder, in material compliance with applicable Laws. Regulations, GMPs and in strict compliance with the Specifications. CSC shall, at its own expense, maintain any and all licenses, permits and consents (including, without limitation, facility licenses and permits) required by any governmental authority, Laws, Regulations and GMPs necessary or required to produce, manufacture, fill, test, package, label, store, ship, supply, dispose and otherwise handle the Product.

- 28. The quality control Specifications are defined in section 1.36 of the Agreement as "the specifications for the Ingredient Product and the Finished Product set forth in Exhibit A attached hereto or such other specifications as may be established from time to time in accordance with Section 3.8 hereof."
- 29. The reference to Exhibit A in section 1.36 of the Agreement was a typographical error, and should have said Exhibit B. Elsewhere in the Agreement, in Section 3.2, CSC agreed to test the Product at a laboratory (the "Laboratory") that conforms to specifications, including

specific equipment, set forth on "the attached Exhibit A" unless otherwise approved in writing by BPP. Exhibit A is entitled "Laboratory Specs/Equipment."

- 30. Although the Specifications were not completed when the Agreement was signed, there was a space left for them following the Agreement, with an "Exhibit B" cover page entitled "Specifications for the Product."
- 31. Pursuant to section 3.8 of the Agreement, BPP had the right to "amend or supplement the Specifications unilaterally at any time for the purpose of complying with Laws, Regulations, and GMPs."
- 32. BPP transmitted the Specifications to CSC in December 2005, and in keeping with the typographical error in the Agreement, the Specifications were originally entitled "Appendix A Quality Assurance, Production Controls and Specifications."
- 33. CSC accepted the Specifications sent by BPP in December 2005. At no time over the next 19 months did CSC purport to reject the Specifications. Rather, CSC repeatedly expressed its desire to provide superior product and exceed all standards.
- 34. In February 2006, BPP made minor revisions to the Specifications and transmitted the revised Specifications to CSC; these were correctly entitled "Exhibit B Specifications for the Product." At no time over the next 17 months did CSC purport to reject the revised Specifications. Indeed, CSC was asked several times if it had any comment on these Specifications and made no reply. A true and correct copy of the Specifications is attached to the Complaint as Exhibit B.
- 35. Despite CSC's longstanding and documented receipt of the quality control Specifications for the Product, CSC responded (belatedly) to BPP's June 8, 2007 notice of

default letter by claiming that the only specifications applicable to the Product are the "laboratory specs/equipment" document found at Exhibit A to the Agreement.

- 36. Although CSC repeatedly told BPP that the Product would be manufactured in accordance with cGMP, it was clear in the year after the Agreement was signed that CSC was not living up to these assurances. For example, beginning in November 2005, BPP received testing reports from CSC that indicated widely varying and high levels of microbiological content and possible contamination of Product manufactured by CSC. The production consisted of more than seven metric tons of the Product. If CSC had been in compliance with cGMP, it could have traced the source of the high bacteria levels by reference to batch records and other tracking documentation required by cGMP. CSC could not determine the source of the possible contamination, however, because it had not adequately prepared or maintained such records.
- 37. Rather than dispose of this Product, CSC proposed to irradiate the Product and thereby vastly reduce the microbiological levels, so that the Product could then be distributed for sale.
- BPP tried to work with CSC in addressing the contamination problem. Ultimately, BPP and CSC and their counsel met in New York, New York on August 23, 2006 to discuss these and other issues regarding CSC's performance of the Agreement. conclusion of that meeting CSC agreed, in writing, that CSC would deliver to BPP standard operating procedures ("SOPs") for the irradiation and handling of the Product, which were to be approved in writing by BPP, together with a complete inventory of all existing Product. In addition, once the SOPs were approved, all existing Product (with certain possible exceptions) would be irradiated by a third party in accordance with an agreed methodology. Finally, prior to the sales of any irradiated Product, CSC would deliver to BPP a letter from a recognized expert

stating that applicable rules and regulations permit sales of irradiated Product and that the irradiated Product has been labeled in accordance with such rules and regulations. A copy of the August 23, 2006 letter setting forth CSC's undertakings with respect to the irradiation and other performance issues is attached to the Complaint as Exhibit C.

- 39. Prior to the August 2006 meeting, BPP had advised CSC at various times that in accordance with the Agreement CSC was obligated to meet the requirements of proposed 21 CFR Parts 111 and 112, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements (the "Dietary Supplement Regulations").
- 40. During the meeting on August 23, 2006, CSC would not acknowledge its obligation to comply with the Dietary Supplement Regulations, and said it would give the topic further consideration. On October 9, 2006, BPP sent an email to Caudill at CSC and, with reference to the Dietary Supplement Regulations and the quality control Specifications, said:

Although we believe that your additional assurance is not technically necessary, as these items are already required in the contract, we wanted to give you the opportunity to comment on them to make sure that you were capable of fulfilling all of the requirements. Thus a written confirmation that you have carefully examined all parts of the FDA's proposed cGMPs for supplements and the BPP's requirements and specifications and will comply with all of them for any future production is desirable.

41. CSC did not immediately respond. On October 13, 2006, BPP sent a letter to Caudill that included a copy of the October 9, 2006 email. Referring again to the August 23, 2006 meeting, BPP stated:

We specifically requested your confirmation that CSC would strictly adhere to the FDA's proposed GMPs for dietary supplements and the specifics in the Exhibit B of the contract between BPP and CSC. Although we believe that these are well within the terms of the existing contract, and thus your agreement is not technically required, we wanted to make sure that you fully understood and were

committed to adherence to these requirements. . . . More than six weeks have passed [since the August 23 meeting], and we have not received your response.

42. By email dated November 14, 2006, referencing BPP's October 13 letter, Caudill told CSC that he was sending production and GMP documents to BPP:

I can assure you that these GMPs meet or exceed the requirements in the Part II Department of Health and Humans Services, Food and Drug Administration, 21 CFR Parts 111 and 112 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements; Proposed Rule [the Dietary Supplement Regulations].

43. Despite CSC's acknowledgment and representation that it was meeting or exceeding the Dietary Supplement Regulations, CSC responded (belatedly) to BPP's June 8, 2007 notice of default letter by claiming that it was not subject to those regulations but that it would "discuss obligations with respect to compliance with 21 CFR and other Regulations with respect to the manufacture of the Product."

### Labeling and Packaging

- 44. The Agreement defines "Labeling" in section 1.21 as "any and all material used to label either the Product, the Packaging or any promotional materials." "Packaging" is defined in section 1.30 as "all material used in packaging, promotional materials or accompanying the Product..."
  - 45. Section 3.4 (Packaging; Expiration Dating) of the Agreement provides:

CSC agrees, and will require purchasers of the Product for resale in the retail market, to label and package all Product with Labeling and Packaging approved in advance and in writing by BPP, including with respect to expiration dating and use of Trademarks. In addition, any claims that CSC or any such purchaser intends to make on the Labeling and/or Packaging of the Product with respect to health benefits of the Product must be pre-approved by BPP as required by Section 4.3(b) hereof.

- 46. CSC was also required to obtain "BPP's prior express written approval of any claims, including, without limitation, any health claims or claims asserting that the Product is beneficial to a consumer, that CSC intends to make with respect to the Product" (section 4.3(b) of the Agreement) and CSC agreed that it "shall not use" the John Hopkins University name in any Labeling, Packaging or other promotional materials without BPP's and JHU's prior express written consent (section 4.4 of the Agreement).
- 47. Despite CSC's clear and unambiguous obligation to obtain BPP's written, advance approval of Labeling and Packaging, CSC repeatedly used or permitted to be used Labeling and Packaging that was not approved in advance by BPP. In addition, with respect to certain proposed labels that BPP reviewed and expressly rejected, such labels were thereafter used anyway.

### **Inspection and Audit**

- 48. Pursuant to section 3.6 of the Agreement, BPP has a right to inspect CSC's facilities "for the purpose of making quality assurance audits of those facilities and of the procedure and process used by CSC in performing its obligations under this Agreement."
- 49. The Agreement also required CSC to "maintain in such form readily available and comprehendible to BPP, all records relating to the production, manufacture, packaging, labeling, storage, shipment, supplying and disposition of each Product batch." Section 6.2 (Manufacturing Records). "Records" are defined as "complete and accurate records, files and books of account, including, without limitation, Laboratory Records, containing all data reasonably required for a full and accurate verification of the performance of [CSC's] obligations under this Agreement." Section 6.1 (Records).

- 50. BPP also has the right under the Agreement to "cause to have audited and make copies of any Records . . . to confirm CSC's compliance with the Agreement." Section 6.4 (Audit).
- 51. In November 2006, CSC delivered to BPP documentation relating to CSC's manufacture and production of the Product. In delivering these materials, CSC stated that its GMPs "meet or exceed" the requirements of the Dietary Supplement Regulations.
- 52. BPP retained a consultant, Mr. Carl Reynolds, to review the CSC documentation. Mr. Reynolds retired from the U.S. Food and Drug Administration in 1999 after more than 36 years with the agency. At the time of his retirement he was Director, Officer of Field Programs, Center for Food Safety and Applied Nutrition in Washington, D.C. Mr. Reynolds is an approved auditor of the Natural Products Association GMP Certification Program.
- 53. In his March 16, 2007 report (the "March 16 Report"), Mr. Reynolds listed 20 different areas of requisite GMP documentation that were not provided by CSC. He concluded that CSC's documents did not establish compliance with either current Good Manufacturing Practices as set forth in the Dietary Supplement Regulations or the Specifications.
- 54. CSC is headquartered in Louisville, Kentucky, but it does not manufacture SGS at its facilities there. Rather, SGS was manufactured and planned for manufacture in other locations, including Texas, Minnesota, Kansas, and Germany. CSC does store SGS packed for distribution as an ingredient as well as SGS-containing products in Louisville.
- 55. As described above, sections 6.2 and 6.1 of the Agreement obligated CSC to maintain in a form "readily available and comprehendible to BPP" all Records relating to the production, manufacture, packaging, labeling, storage, shipment, supplying and disposition of

each Product batch, as well as all data reasonably required for a full and accurate verification of the performance of its obligations.

- 56. By letter dated March 23, 2007, BPP forwarded a copy of the March 16 Report (without exhibits) to CSC, and notified CSC that BPP intended to audit CSC's compliance with GMP and the Specifications (the "Audit Notice"). The Audit Notice stated that the audit would include an inspection of the CSC Laboratories and Records. A true and correct copy of the Audit Notice is attached to the Complaint as Exhibit D.
- 57. The Audit Notice specified many of the Records and materials that the audit team intended to review, and told CSC that it should "have available for inspection any documents that are described in detail on pages 3 and 4" of the March 16 Report, "together with all Laboratory Records and testing data."
- 58. The Audit Notice also advised CSC that it should have ready for inspection and review the current GMP documentation in connection with a planned new Product, called SGS-200, as well as Product samples, and all prior and planned labels that had been or would be used for the Product.
- 59. By letter dated April 11, 2007, CSC's counsel proposed a new sublicensing agreement to BPP's counsel, by which CSC would be permitted to use the BPP patent rights and Know-How, but not the trademarks, in exchange for royalty payments from CSC. The proposed arrangement did not contain any right of BPP to audit or inspect the CSC manufacturing and production facilities.
- 60. BPP advised CSC that it was willing to enter into such a new agreement, provided that, among other items in lieu of BPP's audit and inspection rights CSC agreed to have a

reputable third party certify that the SGS-containing products have been manufactured, filled, stored, shipped and handled in accordance with cGMPs.

- 61. CSC did not respond or object to the Audit Notice. Rather, it sought and received, to a limited extent, a delay in the actual dates of the audit, which went forward from April 25 26, 2007. The auditors also visited JLM Pharmatech, Inc. ("JLM") in Seymour, Indiana on April 27, 2007. JLM is a CSC subcontractor that has a limited role with respect to the production of SGS; it received SGS products from other manufacturing facilities and blends it before packing it in bulk.
- 62. The audit of the CSC facilities concluded that CSC is not operating in accordance with either GMP or the Specifications. In his May 31, 2007 report (the "Audit Report"), Mr. Reynolds found no change in the documentation deficiencies he had listed in his March 16 Report. Despite the clear identification of documents to be inspected set forth in the Audit Notice and the requirements of the Agreement:

The only documentation that was available regarding the GMP status of the manufacturing facilities was that previously provided and reviewed and evaluated in my March 26 [sic], 2007 report. The firm [CSC] did not have copies of GMP policies and procedures. The firm did not have an index of said documentation for review. Caudill [CSC] was not able to demonstrate that SGS has been made in compliance with cGMP and was not able to provide any assurance that the company or its manufacturing partners were prepared or in a position to follow the 2003 proposed dietary supplement cGMPs.

A true and correct copy of the Audit Report (without exhibits) is attached to the Complaint as Exhibit E.

63. The Audit Report also found that CSC was not in compliance with the Specifications. For example, Section 1 of the Specifications requires CSC to have a quality control unit to ensure (among other things) that the manufacturing operations for the Product are

performed properly, and to approve or reject products manufactured, processed, packed, or consigned to others. The Audit Report found, however, "there is no fully, functioning Quality Unit" at CSC and that, to the extent a CSC representative has observed the manufacture and packaging of the Product by others, "there seems to have been no involvement of the quality control unit in evaluating or determining compliance by the 3rd party manufacturing facilities" with the Dietary Supplement Regulations.

### 64. In his conclusions, Mr. Reynolds stated:

Clearly, the company could not provide documentation establishing (1) that it is in compliance with the 2003 proposed dietary supplement cGMPs, (2) that the company has even made an effort to achieve such compliance, or (3) that the company understood what policies and practices were necessary to achieve compliance with cGMPs or the 2003 proposed cGMPs. In fact, in light of [CSC employee] Mr. Ashurst's comments with respect to the 1997 "advance notice" cGMPs, it seemed clear that procedures designed to be fully compliant with the 2003 proposal are not now and have never been in place anywhere along the current manufacturing chain. Similarly, it is equally clear that SGS is not manufactured in accordance with Product Specifications.

#### 65. The Audit Report closed with the following statement:

Documented policies and procedures and supporting records are the cornerstone of cGMP compliance. An SOP should exist for operating or controlling each piece of equipment, system or process that must be cleaned, maintained, calibrated, or otherwise affects the finished product. Documentation and records must be complete, understandable and demonstrate that a firm's policies and procedures were followed to ensure a product meets its purported identity, composition, strength, quality and purity. With the possible exception of JLM, information was not provided that allows me to conclude that the manufacturing steps performed by [CSC subcontractors] were done in compliance with the provisions of proposed 21 CFR Parts 111 and 112.

#### Notice of Events of Default

- 66. Section 10.2(a) of the Agreement provides in relevant part that BPP may terminate it for an "Event of Default which CSC has not cured to the reasonable satisfaction of BPP... within 30 days of BPP's written notice" to CSC.
- 67. Section 10.3 states that "[e]ach of the following events shall constitute an 'Event of Default' by CSC" including:
  - (e) <u>Quality Control</u>: material breach of an obligation relating to the Laboratory or manufacture of the Product;
  - (f) <u>Material Breach</u>: any other material breach of this Agreement.
- 68. By letter dated June 8, 2007, BPP notified CSC that CSC was in default under both of the above provisions. The BPP letter (the "Default Notice") enclosed a copy of the Audit Report. In addition to the breaches relating to the manufacturing standards, facilities, product specifications, and records as described in the Audit Report, the Termination Letter listed more than a dozen other material breaches relating to labeling, use of health claims, product samples, marketing, customer communication files, and failure to comply with specific obligations, confirmed by CSC in the August 23, 2006 letter, regarding irradiation, inventory, and labeling of the Product. A true and correct copy of the Default Notice, without its enclosures, is attached to the Complaint as Exhibit F. Most of the breaches listed in the Default Notice had been the subject of previous, but failed, efforts by BPP to obtain CSC's compliance.
- 69. In accordance with the Agreement, the Default Notice stated that the termination of the Agreement would not occur if within 30 days from the notice "CSC cures the Events of Default to the reasonable satisfaction of BPP...."
- 70. In the 30 days that followed the Default Notice (the "Cure Period"), CSC did not tell BPP that CSC would cure or attempt to cure any of the Events of Default set forth in the Default Notice.

- During the Cure Period, CSC did not write to BPP to dispute, reject, or take issue 71. in any way with the Events of Default set forth in the Default Notice.
- Pursuant to the Agreement, the Default Notice stated that in the absence of cure 72. by CSC of its Events of Default, the Agreement would terminate effective on July 12, 2007 (the "Effective Date").
- On or about July 10, 2007 CSC's counsel, Patrick Welsh, contacted BPP's 73. counsel, Floyd Wittlin, to request a short extension of the Effective Date set forth in the Default Notice in order to facilitate the continued negotiation of a possible new agreement, which would commence immediately and replace the existing Agreement.
- 74. By letter dated July 11, 2007, BPP agreed to extend the Effective Date to July 21, 2007 "for the sole purpose of giving the parties time to negotiate a new Sublicense, Manufacture and Distribution Agreement and for no other purpose." The letter -- which referred to the Default Notice as the "Letter" -- continued:

If, on or before July 20, 2007, BPP and CSC enter into a new Sublicense, Manufacture and Distribution Agreement. then BPP will withdraw the Letter. If, on or before July 20, 2007, BPP and CSC do not enter into a new Sublicense, Manufacture and Distribution Agreement, then the Letter shall continue in effect and the Effective Date shall be July 21, 2007. Except as hereby modified, the Letter remains unchanged and in full force and effect.

A true and correct copy of the July 11, 2007 letter is attached to the Complaint as Exhibit G.

- 75. BPP and CSC did not enter into a new licensing agreement on or before July 20, 2007.
- 76. On the afternoon of July 20, 2007, Welsh (CSC's counsel) telephoned Wittlin (BPP's counsel) in New York and advised him that CSC was not capable of complying with BPP's requirement that, prior to any further sales of SGS-containing products, CSC must provide

BPP with a third party certification that the products have been manufactured, filled, stored, shipped and handled in accordance with specifications, proposed by BPP, that incorporated the Dietary Supplement Regulations.

- 77. At 4:57 pm (EDT) on July 20, 2007, Welsh sent Wittlin a letter signed by Caudill on CSC letterhead, and addressed to BPP, which purported to take issue with all aspects of BPP's Default Notice, with one exception relating to insurance. A true and correct copy of the CSC letter is attached to the Complaint as Exhibit H.
- The CSC July 20, 2007 letter states that, contrary to the Agreement and CSC's 78. own prior statements and conduct, CSC was not subject to either the Specifications or the Dietary Supplement Regulations. Seemingly oblivious to its own inconsistencies, CSC stated that CSC would continue to manufacture and sell the Product because, in CSC's view, the Agreement had not been terminated.
- In accordance with the Agreement, the Default Notice, and BPP's July 11, 2007 79. letter, the Agreement terminated on July 21, 2007.

#### Reversion of Rights to BPP

- Section 10.4(a) of the Agreement provides that upon termination of the 80. Agreement, "all rights herein granted to CSC shall revert to BPP and CSC shall cease the production, manufacture, distribution, sale, use or advertisement of the Product."
- 81. Section 10.4(b) and (c) of the Agreement permit CSC to sell its existing inventory of SGS-containing products during the 90-day period following termination of the Agreement, but only if CSC promptly delivers a schedule of its existing inventory to BPP, and BPP then declines to purchase that inventory. CSC has failed to deliver a schedule of its existing inventory to BPP and therefore has no right to sell its inventory of the SGS-containing products.

- Under section 10.4(c) of the Agreement, CSC agreed that it would not promote or 82. advertise the Product following the termination of the Agreement.
- Section 10.4(d) of the Agreement requires that, upon termination of the 83. Agreement, CSC shall return the "Confidential Information" of BPP defined in Section 13.2 of the Agreement as "such party's proprietary, technical information, marketing information, scientific data, "confidential" marked or designated information, and all other information which a reasonable person would treat confidentially."

#### **Unpaid Royalties**

- CSC agreed to make quarterly royalty payments to BPP pursuant to section 5.2 of 84. the Agreement. CSC has failed to pay BPP the April - June 2007 royalty payment. This also constitutes an Event of Default under the Agreement.
- CSC agreed to pay a minimum royalty to BPP of \$100,000 for the year ending 85. December 6, 2007, less the amount CSC has paid in actual royalties for the same period. With the termination of the Agreement effective July 21, 2007, CSC owes -- and has not paid -- BPP a prorated minimum royalty amount of \$56,600.

## As and For a First Cause of Action Against Defendant (Breach of Contract)

- Plaintiff BPP repeats and realleges each and every allegation in paragraphs 1 through 85 of this Complaint as if fully set forth herein.
  - The Agreement constituted a valid and binding contract between BPP and CSC. 87.
  - BPP fully and faithfully performed all its obligations under the Agreement. 88.
- CSC materially breached the terms of the Agreement and did not cure or attempt 89. to cure its defaults in accordance with the terms of the Agreement.

- 90. CSC further breached its obligation to pay the contractually specified royalty payments for the second quarter of 2007 and the prorated minimum royalty payments due under the terminated Agreement.
- 91. As a direct and proximate result of the foregoing, BPP has suffered damages in an amount to be determined at trial, but in no event less than \$60,000.

# As and For a Second Cause of Action Against Defendant (Breach of Contract)

- 92. Plaintiff BPP repeats and realleges each and every allegation in paragraphs 1 through 91 of this Complaint as if fully set forth herein.
  - 93. The Agreement constituted a valid and binding contract between BPP and CSC.
- 94. BPP fully and faithfully performed all its obligations under the Agreement, including conveying its proprietary and confidential information regarding SGS-containing products to CSC, and permitting CSC to use BPP's patents, trademarks, Know-How and other intangible property and rights.
- 95. CSC has breached the post-termination provisions of the Agreement by failing, without justification, to cease the production, manufacture, distribution, sale, use or advertisement of the Product, constituting an unauthorized use of BPP's proprietary and confidential information, patents, trademarks, Know-How and other intangible property and rights.
- 96. CSC has further breached the post-termination provisions of the Agreement by failing to return BPP's Confidential Information in accordance with Section 10.4(d) of the Agreement.
- 97. As a direct and proximate result of the foregoing, BPP is now suffering and will continue to suffer irreparable injury.

# <u>As and For a Third Cause of Action Against Defendant</u> (Unjust Enrichment)

- 98. Plaintiff BPP repeats and realleges each and every allegation in paragraphs 1 through 97 of this Complaint as if fully set forth herein.
- 99. BPP conveyed its proprietary and confidential information regarding SGS-containing products to CSC, relying on CSC's promise that upon termination of the Agreement, all rights granted to CSC would revert to BPP "and CSC shall cease the production, manufacture, distribution, sale, use or advertisement of the Product."
- 100. CSC has retained and continues the use of BPP's proprietary and confidential information, patents, trademarks, Know-How and other intangible property and rights despite the termination of the Agreement.
- 101. As a direct and proximate result of the foregoing, CSC has been unjustly enriched at BPP's expense, and in equity and good conscience CSC should make restitution to BPP, in an amount to be determined at trial.

# As and For a Fourth Cause of Action Against Defendant (Trademark Infringement under 15 U.S.C. § 1125(a)))

- 102. Plaintiff BPP repeats and realleges each and every allegation in paragraphs 1 through 101 of this Complaint as if fully set forth herein.
- 103. BPP has applied for registration of its SGS logo (referenced herein as "SGS logo") with the United States Patent and Trademark Office ("USPTO"), which was filed on October 27, 2005. In addition, the Brassica Protective Product logo (the "BPP® logo") is registered upon the Principal register of the USPTO as United States Registration No. 2,252,002, and was issued on June 8, 1999.
- 104. CSC continues to use and sell SGS-containing products bearing the SGS logo, including the promotion and sale of such products on CSC's website http://www.yoursgs.com/.

A true and correct copy of two pages from the CSC website is attached to the Complaint as Exhibit I. CSC's ongoing use of the SGS logo in conjunction with the sale of SGS-containing products infringes the rights of BPP in the SGS logo.

- CSC's use of the SGS logo in connection with SGS-containing products is likely to cause confusion, mistake or deception as to the source, origin or sponsorship of CSC's goods in that the public and others are likely to wrongly believe that CSC's goods are genuine BPP goods, and are sponsored by, or approved by, or licensed by, or affiliated with or in some way legitimately connected with BPP, all to BPP's irreparable harm.
- 106. BPP has no control over the quality of goods sold by CSC, and because of the confusion as to the source, origin or sponsorship engendered by CSC, BPP's valuable goodwill in respect to the SGS logo will be diminished.
- Upon information and belief, despite the fact that CSC has knowledge that the trademark laws of the United States protect the SGS logo, CSC is nevertheless willfully infringing the SGS logo.
- As a direct and proximate result of the foregoing, BPP is now suffering and will continue to suffer irreparable injury. BPP has also suffered damages as a result of CSC's trademark infringement, in an amount to be determined by the Court.

# As and For a Fifth Cause of Action Against Defendant (Tarnishment under 15 U.S.C. § 1125(a))

- Plaintiff BPP repeats and realleges each and every allegation in paragraphs 1 through 108 of this Complaint as if fully set forth herein.
- CSC deceptively promotes, offers for sale and sells SGS-containing products, affixed with the SGS logo, that are not genuine BPP goods, but nevertheless falsely represents those goods to be genuine BPP goods.

- More specifically, CSC deceptively promotes, offers for sale and sells SGScontaining products bearing the SGS logo as genuine BPP goods, when those goods are of a lesser quality because they are not manufactured in accordance with BPP's quality control requirements.
- As a direct and proximate result of the foregoing, BPP is now suffering and will continue to suffer irreparable injury. BPP has also suffered damages as a result of CSC's conduct, in an amount to be determined by the Court.

# As and For a Sixth Cause of Action Against Defendant (Misappropriation of Proprietary and Confidential Information)

- Plaintiff BPP repeats and realleges each and every allegation in paragraphs 1 through 112 of this Complaint as if fully set forth herein.
- CSC has obtained BPP's proprietary and confidential information pursuant to the 114. Agreement.
- 115. BPP has taken reasonable steps to protect its proprietary and confidential information by stating in Section 10.3(d) of the Agreement that CSC is prohibited from using BPP's proprietary and confidential information upon termination of the Agreement.
- BPP has the right to exclusive ownership, enjoyment, and use of its proprietary and confidential information.
- CSC is now using BPP's proprietary and confidential information in breach of the post-termination provisions of the Agreement.
- As a direct and proximate result of the foregoing, BPP is now suffering and will continue to suffer irreparable injury. BPP has also suffered direct and consequential harm as a result of CSC's misappropriation of BPP's proprietary and confidential information and is entitled to damages.

# As and For a Seventh Cause of Action Against Defendant (New York Unfair Competition - N.Y.G.B.L. §§ 349 and 350)

- 119. Plaintiff BPP repeats and realleges each and every allegation in paragraphs 1 through 118 of this Complaint as if fully set forth herein.
- 120. CSC sells or distributes SGS-containing products to customers in the State of New York and elsewhere. In the course of its business, CSC is engaged in consumer-oriented acts that are misleading in a material way, and that cause injury to BPP.
- 121. CSC is manufacturing, distributing and selling SGS-containing products bearing the SGS logo even though they are not genuine BPP products and do not adhere to BPP's quality control requirements.
- 122. Consumers are deceived into believing that the SGS-containing products sold by CSC with the SGS logo are genuine BPP goods but instead receive goods that are of a lesser quality.
- 123. CSC is also exploiting BPP's proprietary and confidential information in breach of the post-termination provisions of the Agreement and therefore misappropriating a commercial advantage belonging to BPP.
- 124. As a direct and proximate result of the foregoing, BPP is now suffering and will continue to suffer irreparable injury. BPP has also suffered damages as a result of CSC's unfair competition, in an amount to be determined by the Court.

# As and For a Eight Cause of Action Against Defendant (Common Law Unfair Competition)

- 125. Plaintiff BPP repeats and realleges each and every allegation in paragraphs 1 through 124 of this Complaint as if fully set forth herein.
- 126. BPP has invested substantial time, effort, resources, and money in its SGS logo and in maintaining its proprietary and confidential information.

- 128. Upon information and belief, CSC continues to use the SGS logo and BPP's proprietary and confidential information.
- 129. CSC will gain an unfair advantage in the marketplace by wrongly using the SGS logo and BPP's proprietary and confidential information.
  - 130. CSC's intentional use of the SGS logo operates to confuse and mislead customers.
- 131. BPP has been, and is likely to be further, damaged by CSC's improper and intentional use of the SGS logo and BPP's proprietary and confidential information.
- 132. As a direct and proximate result of the foregoing, BPP is now suffering and will continue to suffer irreparable injury. BPP has also suffered damages as a result of CSC's unfair competition, in an amount to be determined by the Court.

WHEREFORE, plaintiff Brassica Protection Products LLC respectfully demands judgment as follows:

ON THE FIRST CAUSE OF ACTION: for judgment against defendant Caudill Seed & Warehouse Co., Inc. in an amount to be determined by the Court;

ON THE SECOND CAUSE OF ACTION: that Defendant, its agents, representatives and all other persons acting in concert with it be enjoined and restrained, during the pendency of this action, and permanently thereafter, from the continued use and exploitation of plaintiff Brassica Protection Products' rights granted to defendant under the Agreement, and further ordering defendant to cease the production, manufacture, distribution, sale, use or advertisement of the Product and further ordering defendant to return the Confidential Information procured under the terms of the Agreement;

ON THE THIRD CAUSE OF ACTION: for judgment against defendant Caudill Seed & Warehouse Co., Inc. in an amount to be determined by the Court;

ON THE FOURTH CAUSE OF ACTION: that Defendant, its agents, representatives and all other persons acting in concert with it be enjoined and restrained, during the pendency of this action, and permanently thereafter, from the continued use and exploitation of plaintiff Brassica Protection Products' trademarks and SGS logo, together with damages and an award of plaintiff's reasonable attorneys' fees and costs, in amounts to be determined by the Court;

ON THE FIFTH CAUSE OF ACTION: that Defendant, its agents, representatives and all other persons acting in concert with it be enjoined and restrained, during the pendency of this action, and permanently thereafter, from the continued use and exploitation of plaintiff Brassica Protection Products' trademarks or SGS logo, from representing to anyone that any SGS-containing products it sells or distributes are genuine BPP goods and from distributing any SGS-containing products shipped or sold in packaging reflecting the BPP trademark or SGS logo, together with damages and an award of plaintiff's reasonable attorneys' fees and costs, in amounts to be determined by the Court;

ON THE SIXTH CAUSE OF ACTION: that Defendant, its agents, representatives and all other persons acting in concert with it be enjoined and restrained, during the pendency of this action, and permanently thereafter, from the continued use and exploitation of plaintiff Brassica Protection Products' confidential and proprietary information previously supplied to defendant under the terminated Agreement by ordering defendant to return plaintiff's proprietary and confidential information and cease the production, manufacture, distribution, sale, use or advertisement of the Product; and for judgment against the defendant in the amount to be determined by the Court;

ON THE SEVENTH CAUSE OF ACTION: that Defendant, its agents, representatives and all other persons acting in concert with it be enjoined and restrained, during the pendency of this action, and permanently thereafter, from the continued use and exploitation of plaintiff Brassica Protection Products' proprietary and confidential information previously supplied to defendant under the terminated Agreement and Plaintiff Brassica Protection Products' trademarks and SGS logo and for judgment against defendant Caudill Seed & Warehouse Co., Inc. in an amount to be determined by the Court and for trebling of damages if the Court finds that the Defendant willfully or knowingly violated N.Y.G.B.L. § 349 and § 350, and plaintiff's reasonable attorneys' fees and costs, in amounts to be determined by the Court;

ON THE EIGHTH CAUSE OF ACTION: that Defendant, its agents, representatives and all other persons acting in concert with it be enjoined and restrained, during the pendency of this action, and permanently thereafter, from the continued use and exploitation of plaintiff Brassica Protection Products' proprietary and confidential information previously supplied to defendant under the terminated Agreement and Plaintiff Brassica Protection Products' trademarks and SGS logo and for judgment against defendant Caudill Seed & Warehouse Co., Inc. in an amount to be determined by the Court.

Dated: New York, New York August 6, 2007

Respectfully submitted,

Edward L. Powers

BINGHAM McCUTCHEN LLP

Attorneys for Plaintiff 399 Park Avenue

New York, New York 10022

(212) 705-7000

Exhibit A

SUBLICENSE, MANUFACTURE AND DISTRIBUTION AGREEMENT....

BY AND BETWEEN

BRASSICA PROTECTION PRODUCTS LLC

AND

CAUDILL SEED & WAREHOUSE CO., INC. d/b/a CAUDILL SEED CO.

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#### AGREEMENT

This SUBLICENSE, MANUFACTURE AND DISTRIBUTION AGREEMENT (the "Agreement") is made as of December 6, 2004, by and between BRASSICA PROTECTION PRODUCTS LLC, a Delaware limited liability company ("BPP") located at 600 East Lombard Street, Suite 503, Baltimore, Maryland 21202, and CAUDILL SEED & WAREHOUSE CO., INC. d/b/a CAUDILL SEED CO., a Kentucky corporation ("CSC") located at 1402 W. Main Street, Louisville, Kentucky 40203.

#### WITNESSETH

WHEREAS, BPP has the exclusive worldwide license to use and exploit certain BPP Patents and Patent Rights (as hereinafter defined) from The Johns Hopkins University ("JHU"); and

WHEREAS, subject to the terms and conditions below, BPP wishes to grant to CSC and CSC is willing to accept from BPP, a non-exclusive sublicense to use the BPP Patents, Patent Rights and BPP Know-How, and a non-exclusive license to use the Trademarks (as hereinafter defined) for the sole and exclusive purpose of manufacturing, distributing and selling the Product (as hereinafter defined) in the Territory (as hereinafter defined).

NOW THEREFORE, in consideration of the mutual covenants and conditions contained in this Agreement, and other good and valuable consideration the receipt of which is hereby acknowledged, and intending to be legally bound hereby, the parties agree as follows:

# ARTICLE 1 DEFINITIONS

- 1.1. "Act" means the Federal Food Drug and Cosmetic Act (21 U.S.C. Section 301 et seq.) as amended from time to time.
  - 1.2. "Adverse Events" shall have the meaning set forth in Section 8.2.
- 1.3. "Affiliate" means any corporation, company, partnership, licensee, joint venture or other entity which controls, is controlled by or is under common control with CSC. The term "control" means the direct or indirect ownership of at least fifty percent (50%) of the voting or equity interests or the power or right to direct the management and affairs of the business whether through the ownership of voting securities, by contract, resolution, regulation or otherwise.
- 1.4. "BPP Know-How" means all current and future data and proprietary rights of any type whatsoever (other than patents or patent applications, including the BPP Patents or Patent Rights), in any tangible or intangible form whatsoever, that is owned (or to the extent owned) by BPP or that BPP has the unrestricted right to use, that is material to the production, manufacture, storage, filling, packaging and shipping of the Product, including, without limitation, technology, Labeling, inventions, practices, methods, techniques, specifications, drawings, plans, formulations, formulae, knowledge, skill, experience, technical and non-